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EXAMINER

IBRAHIM, MEDINA AHMED

ART UNIT	PAPER NUMBER
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1638

DATE MAILED: 06/01/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/850,091

Applicant(s)

MATSUNAGA ET AL.

Examiner

Medina A Ibrahim

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 21 May 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-26 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-26 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 13) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.
a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ 6) ☐ Other: _____

DETAILED ACTION

Receipt is acknowledged of Applicants' response to the final Office action mailed 01/16/04. However, upon further search and consideration, it has been determined that the finality of the rejection of the last Office action be withdrawn. The indicated allowability of claims 4-5, 9-10 and 25-26 has been withdrawn. The Office action contains NEW GROUNDS OF REJECTIONS and is made non-final. Any inconvenience the delay may have caused Applicant is deeply regretted.

Applicant's response of 04/13/04 has been considered.

Claims 1-26 are pending and are examined.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 22-23 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 22-23 are indefinite in the recitation of "using" without any active, positive steps delimiting how this use is actually practiced.

At claim 22, "dedifferentiation efficiency" does not make sense. If Applicant intends ---redifferentiation efficiency---, the claim should be amended to recite so.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the

art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-3, 5-8, 10-24 and 26 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The claims are broadly drawn to a method for introducing a desired gene into a plant, comprising introducing a vector comprising a CK11 gene as a selectable marker gene under the control of a light inducible promoter, said method wherein the vector further comprises any removable DNA and a method for producing a transgenic plant free from the influence of a selectable marker comprising transforming said plant with said vector, wherein the selectable marker gene, and not the desired gene, is positioned such that it behaves integrally with the removable DNA, and transgenic plant and plant cells produced by said method.

Applicant describes a vector comprising a cytokinin signal transduction gene from *Arabidopsis thaliana* designated as "CK11" gene as a selectable marker gene under the control of a light-inducible, a method for introducing a desired gene into a plant with said vector, and a method that employs said vector further comprising the yeast site-specific recombinase system to cause removal of the selectable marker gene. On page 11 of the specification, Applicant states that CK11 is a prior art gene from *Arabidopsis thaliana* that is considered to be a cytokinin receptor gene. However, identifying gene as "CK11" is insufficient to provide the structural and functional

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characteristics necessary to describe the claimed invention for the following reasons: 1) the specification does not describe specific characteristics that distinguish the CKI1 gene from other Arabidopsis cytokinin receptor genes. 2) Prior art search reveals a single CKI1 gene from Arabidopsis thaliana. 3) It is unclear if CKI1 is a single gene or a gene family. It is also unclear if the gene also exists in other plant species. 3) Neither the prior art nor the instant specification describes how to identify cytokinin receptor genes that functions as selectable markers and with any removable DNA element. Given this lack of written description for the CKI1 gene, the claimed vectors, plants and plant cells comprising said gene and methods that employ said CKI1 gene are similarly not described.

Amending the claims to recite that the CKI1 is a cytokinin signal transduction gene from Arabidopsis thaliana will obviate this rejection.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-4 and 22-25 are rejected under 35 U.S.C. 102(b) as being anticipated by Jefferson (US PAT 5,268, 463).

The claims are directed a method for introducing a gene into a plant comprising introducing into a plant a vector comprising a beta-glucuronidase gene as a selectable marker gene under the control of a ribulose 2-phosphate carboxylase small subunit

promoter, culturing said plant cell into a tissue, selecting a transgenic tissue expressing said beta glucuronidase gene, and regenerating a plant from said transgenic tissue. The claims are also drawn to a method for improving redifferentiation efficiency of a transgenic tissue with said vector.

Jefferson teaches a method of introducing a gene into a plant comprising introducing into tobacco cells a construct comprising GUS gene under the control of rbcS promoter. Jefferson also teaches methods of culturing and selecting transgenic tissues expressing GUS, and regenerating transformed tobacco plants expressing the GUS gene from the transgenic tissues (Example 8 on columns 43-50; Figure). At columns 19 to 20, the cited reference teaches the use of GUS-rbcS gene construct as a reporter system to deliver a desired gene into a plant. The GUS gene is considered both as the desired gene and selectable marker gene. The adventitious shoot redifferentiation and the improved redifferentiation efficiency will be an inherent property of the transgenic tissues expressing the GUS gene. Therefore, Jefferson teaches all claim limitations.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of

the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-3, 5 and 22-24 and 26 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kakimoto et al (Science (1996, vol. 274, pp. 982-985, Applicant's IDS) in view of Redig et al (PHYSIOLOGIA PLANTARUM 99: 89-96. 1997, Applicant's IDS).

The claims are drawn to a method for introducing a gene into a plant comprising introducing into a plant a vector comprising CK11 gene as a selectable marker gene under the control of a ribulose 2-phosphate carboxylase small subunit gene, culturing said plant cell into a tissue, selecting a transgenic tissue expressing said CK11 gene. The claims are also drawn to a method for improving redifferentiation efficiency of a transgenic tissue with said vector.

Kakimoto et al teach a method of introducing a gene into Arabidopsis cells comprising introducing a vector comprising a cytokinin independent gene designated as "CK11" under the control of the CaMV 35S promoter into said plant cells; culturing and selecting transformed tissues that proliferated rapidly and produced many shoots in the absence of cytokinin, and regenerating a fertile transgenic Arabidopsis. Kakimoto

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describes the CKI1 gene as a cytokinin signal transduction gene and shows that the expression of the gene in plant tissues can be visually detected.

Kakimoto et al do not explicitly teach the use of CKI1 gene with a light inducible promoter from a ribulose 2-phosphate carboxylase small subunit gene.

Redig et al teach an ipt, a cytokinin related, gene expressed under the control of a ribulose 2-phosphate carboxylase small subunit promoter. Given the successful expression of the CKI1 gene in transgenic plant cells, and the ability of the CKI1 gene to induce cytokinin production causing rapid cell proliferation and production of many shoots which can be visually detected as taught by Kakimoto, one skilled in the art would have been motivated to use the CKI1 as a selectable marker gene, and with any plant promoter including a ribulose 2-phosphate carboxylase small subunit gene promoter, with a reasonable expectation of success. In addition, there is no known plant deleterious effect associated with the ribulose 2-phosphate carboxylase small subunit gene promoters. Applicant has not shown unexpected results associated with the rbcS gene promoter. Therefore, the claimed invention as a whole was *prima facie* obvious to one skilled in the art at the time this application was filed.

Claims 1-4, 6-9, and 11-25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ebinuma et al (EP 0716 147 A2) in view of Jefferson (US PAT 5,268, 463).

The claims are drawn to a method for introducing a gene into a plant comprising introducing into a plant a vector comprising a desired gene GUS gene as a selectable

marker under the control of a ribulose 2-phosphate carboxylase small subunit (rbcS) promoter, culturing said plant cell into a tissue, selecting a transgenic tissue expressing said GUS gene. The claims are also drawn to said vector further comprising a removable DNA element, wherein the selectable marker gene, and not the desired gene, is positioned such that it behaves integrally with the removable DNA, a method of introducing a gene using said vector, and transgenic plant and plant cells produced by said method. The claims are further drawn to a method for improving redifferentiation efficiency of a transgenic tissue and producing transgenic plants free of selectable marker genes.

Ebinuma et al teach a method of introducing a desired gene into a plant by transforming tobacco cells with a vector comprising a desired gene, a selectable marker gene, and yeast site-specific recombination system as the removable DNA element, wherein the selectable marker gene, and not the desired gene, is positioned such that it behaves integrally with the removable DNA element (Figure 20). Ebinuma also teaches methods for cultivating the transformed plant cells, detecting and selecting desired transgenic tissues, and regenerating transgenic plants that are free from the influence of a marker gene from said transgenic tissues (pages 14-16; Example 5, Table 2). The cited reference also teaches transformation efficiency related with the use of GUS gene (either as a selectable marker or as a desired gene) and the site-specific recombination system (pages 19-20; and Table 3).

Ebinuma et al do not explicitly teach GUS gene under rbcS gene promoter.

Jefferson et al teach the use of GUS-rbcS gene construct as a reporter system to deliver a desired gene into a plant as discussed above. On column 19, Jefferson teaches that light inducible promoters including those from rbcS are useful in the GUS gene expression system. The cited reference further teaches the advantage of the GUS gene offers over other reporter genes such as the ease and economy of GUS assay systems, and the fact that GUS activity may be detected and accurately measured in samples as small as a single cell (columns 8-12).

It would have been obvious to one of skill in the art at the time this application was filed to use the method of producing transgenic plants free from the influence of selectable markers as taught by Ebinuma, and to modify that method by incorporating GUS-rbcS construct as the selectable marker system, to produce transgenic plants with no selectable marker gene, with a reasonable expectation of success. One skilled in the art would have been motivated to use GUS-rbcS gene construct because of the advantages of GUS over other selectable markers as suggested by Jefferson.

Therefore, the claimed invention as a whole was *prima facie* obvious to one skilled in the art at the time this application was filed.

Remarks

No is allowed.

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Contact Information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Medina A. Ibrahim whose telephone number is (571) 272-0797. The Examiner can normally be reached Monday -Thursday from 8:00AM to 5:30PM and every other Friday from 9:00AM to 5:00 PM . Before and After final responses should be directed to fax nos. (703) 872-9306 and (703) 872-9307, respectively.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Dr. Amy Nelson, can be reached at (571) 272-0804.

5/25/04
Mai

Medina A. Ibrahim